



Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-19-0106; NOP-19-03]

RIN 0581-AD98

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (2022 Sunset)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the United States Department of Agriculture's (USDA) organic regulations to implement recommendations from the National Organic Standards Board (NOSB). The rule prohibits fourteen nonorganic ingredients, which are currently allowed in the manufacture of organic processed products. The rule also prohibits two substances (vitamin B₁ and procaine), which are currently allowed in organic crop and livestock production. Finally, the rule renews an allowance for two substances (oxytocin and sucrose octanoate esters) in organic production.

DATES: *Effective Date:* This rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Compliance Dates: The compliance date for the amendments that remove vitamin B₁ and procaine from the National List is March 15, 2023. The compliance date for all other amendments that remove substances from the National List is March 15, 2024. Products in the stream of commerce after the compliance date that are labeled as "organic" or "made with organic (specified ingredients or food group(s))" may contain substances removed in this final rule if manufactured prior to the compliance date. The final rule renews an allowance for two substances (oxytocin and sucrose octanoate esters) in

organic production. This rule maintains the current regulatory structure with regard to these two substances upon publication for up to five years.

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SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary of Agriculture (“Secretary”) established the Agricultural Marketing Service’s (AMS) National Organic Program (NOP) and the USDA organic regulations (65 FR 80547). Within the USDA organic regulations (7 CFR part 205) is the National List of Allowed and Prohibited Substances (or “National List”). The National List identifies the synthetic substances that may be used in organic crop and livestock production as well as the nonsynthetic (natural) substances that may not be used. It also identifies the nonorganic substances that may be used in or on processed organic products.

AMS is finalizing 16 amendments to the National List in accordance with the procedures detailed in the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524). OFPA establishes what may be included on the National List and the procedures that the USDA must follow to amend the National List (7 U.S.C. 6517). OFPA also describes the NOSB’s responsibilities in proposing amendments to the National List, including the criteria for evaluating amendments to the National List (7 U.S.C. 6518).

To remain on the National List, substances must be: (1) Reviewed every five years by the NOSB, a 15-member federal advisory committee; and (2) renewed by the Secretary (7 U.S.C. 6517(e)). This action of NOSB review and USDA renewal is commonly referred to as the “sunset review” or “sunset process.” AMS published information about this process in the *Federal Register* on September 16, 2013 (78 FR

56811). The sunset date (i.e., the date by which the Secretary must renew a substance for the listing to remain valid on the National List) for each substance is included in the NOP Program Handbook (document NOP 5611).

The removal of substances from the National List addresses National Organic Standards Board (NOSB) recommendations submitted to the Secretary after the conclusion of the NOSB's public meetings on October 29, 2015; November 2, 2017; October 26, 2018; and October 30, 2020.

During a 60-day comment period that closed on October 25, 2021, AMS received 60 comments on the proposed rule. See below for a discussion of the comments received and AMS's responses to comments. Comments on the proposed rule can also be viewed through Regulations.gov. Use the search area on the homepage at <https://www.regulations.gov> to enter a keyword, title, or docket ID (the docket number for this rule is AMS-NOP-19-0106).

II. Overview of Amendments

This rule removes fourteen ingredients and two substances from the National List and retains (or “renews”) two substances on the National List. Additional background on the NOSB's review of the substances may be found in the proposed rule (86 FR 47242; August 24, 2021).

This final rule removes the following synthetic substances, which are currently allowed in organic crop and livestock production (7 CFR 205.601 and 205.603):

- Vitamin B₁ (crop production); and
- Procaine (livestock production).

As noted in the DATES section, AMS is providing a one-year implementation period for these changes to provide time for certifying agents to communicate the changes to organic operations and for organic producers to cease use.

Additionally, AMS is removing the following nonorganic ingredients, which are currently allowed in organic handling (§§ 205.605 and 205.606):

- Alginic acid;
- Colors (black currant juice color, blueberry juice color, carrot juice color, cherry juice color, grape juice color, paprika color, pumpkin juice color, turmeric extract color);
- Kelp;
- Konjac flour;
- Sweet potato starch;
- Turkish bay leaves; and
- Whey protein concentrate.

Finally, this rule renews sucrose octanoate esters for organic crop and livestock production and oxytocin for organic livestock production. The new sunset date for the two substances (three listings on the National List) is March 15, 2027.

Below, AMS describes each substance in alphabetical order, sorted by use (i.e., crop production, livestock production, handling). Sucrose octanoate esters is discussed first because it is used in both crop and livestock production. For each substance, AMS outlines the NOSB's sunset review, discusses comments received, and describes the final action by this rule.

Implementation Period. As noted in the DATES section, AMS is providing a one-year implementation period for producers to cease use of vitamin B₁ and procaine. For all other substances removed by this final rule, AMS is providing a two-year implementation period. A shorter implementation period for vitamin B₁ and procaine is appropriate because there is no evidence these substances are currently used in organic production. A 2-year implementation period is provided for organic handling operations to cease use of the nonorganic ingredients (including alginic acid) above. AMS believes

that a two-year implementation period provides certifying agents with the necessary time to communicate the changes to organic operations and for operations to source organic forms of the ingredients (if necessary), revise labels, and/or adjust recipes. Public comment indicated a two-year implementation period would be adequate. AMS notes that while the final rule provides a two-year implementation period, organic handlers may not use nonorganic forms of ingredients when organic forms of the ingredients are commercially available (see 7 CFR 205.301(f)(6)).

Sucrose Octanoate Esters (§ 205.601 and § 205.603)

This final rule renews the allowances for sucrose octanoate esters at 7 CFR 205.601(e)(10) and 205.603(b)(11).¹ Sucrose octanoate esters is a pesticide that targets mites (e.g., *Varroa* mites, a pest that attacks honeybees) and certain soft-bodied insects (e.g., aphids).

NOSB review and recommendation

Following the sunset review of sucrose octanoate esters, the NOSB recommended removing sucrose octanoate esters from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

Prior to the NOSB's 2018 Fall meeting, the NOSB received information indicating there were no current U.S. Environmental Protection Agency (EPA) registrations for sucrose octanoate esters at the time and therefore no approved pesticide applications. Based on this information, the NOSB reasoned that no argument could be made that this substance remains an essential tool for organic production if there was no current legal use consistent with the National List restrictions. The Board then voted to

¹ Sucrose octanoate esters is cited in NOSB recommendation(s) at 7 CFR 205.603(b)(10). The current citation for sucrose octanoate esters is 7 CFR 205.603(b)(11).

remove both the crop use listing (at § 205.601(e)) and the livestock use listing (at § 205.603(b)).^{2,3} In both organic crop and livestock production, sucrose octanoate esters are allowed as an insecticide and parasiticide, with the latter including treatment of *Varroa* mites in honeybees. Honeybees are regulated as livestock under the USDA organic regulations (see definition of “livestock” at § 205.2), allowing substances on the National List for livestock production to be used in organic apiculture (beekeeping).

Comments received

Most comments on the proposed rule related to the proposed removal of sucrose octanoate esters from the National List.

Lack of approved alternatives. Most comments supported keeping sucrose octanoate esters on the National List. Commenters stated that removing this substance would have a negative impact on organic farmers and beekeepers, as it is a primary ingredient in OrganiShield - a common product used in Integrated Pest Management (IPM) systems. Commenters stressed that there is no comparable product on the market that is safe, effective, and approved for use in organic crop and livestock production.

Environmentally friendly pesticide. Commenters noted that the use of sucrose octanoate esters benefits crop-friendly insects such as pollinators, biodegrades rapidly after use, and does not negatively impact the environment. Multiple commenters highlighted that sucrose octanoate esters play a key role as an organic pesticide, specifically in controlling *Varroa* mites.

Change in market situation. Commenters highlighted that the NOSB voted to remove both the crop use listing at § 205.601(e) and the livestock use at § 205.603(b) during the Fall 2018 meeting. The NOSB’s rationale was that sucrose octanoate esters

² National Organic Standards Board, *Sunset Review of Substances Listed at §§205.601 and 205.602*, <https://www.ams.usda.gov/sites/default/files/media/CS2020SunsetFinalRecOct2018.pdf>

³ National Organic Standards Board, *Sunset Review of Substances Listed at §205.603*, <https://www.ams.usda.gov/sites/default/files/media/LS2020SunsetFinalRecOct2018.pdf>

could not be considered an essential tool for organic production if there were no legally approved uses (i.e., there were no active EPA pesticide registrations at the time). Commenters noted that the market situation has changed since the NOSB's 2018 decision, as there have since been new EPA registrations for sucrose octanoate esters.

AMS response

AMS had tentatively suggested removal of sucrose octanoate esters in the proposed rule based on the lack of EPA-approved uses for this substance back when the NOSB recommended its removal in 2018 (86 FR 47242, August 24, 2021). Following the 2018 NOSB meeting, the EPA received product registrations for sucrose octanoate esters in December 2020. Subsequent comments demonstrated that the market situation had changed since the 2018 NOSB recommendation, with recent product registrations and increased use of sucrose octanoate esters. Additionally, comments noted this substance is not harmful to the environment and cited the lack of alternatives approved for organic use. In response to comments identifying the recent registration, increased use, and a lack of alternatives, AMS is not removing sucrose octanoate esters from the National List at §§ 205.601(e)(10) and 205.603(b)(11). The substance will undergo another sunset review prior to the new March 15, 2027 sunset date. At that time, the Board will have another opportunity to evaluate the substance against OFPA criteria considering this recent registration and increase in use.

Vitamin B₁ (§ 205.601)

This final rule amends the National List to prohibit use of synthetic vitamin B₁ in organic crop production by removing vitamin B₁ from 7 CFR 205.601(j)(9).

NOSB review and recommendation

Following the sunset review of vitamin B₁, the NOSB recommended removing vitamin B₁ from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against

criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In support of their sunset review,⁴ the NOSB requested a third-party technical report on the use of vitamins B₁, C, and E in crop production.⁵ The technical report stated these vitamins are generally used for stimulation of crop growth and plant protection but found that previous claims about root growth and reduction of transplant shock associated with vitamin B₁ were largely unsubstantiated outside of a laboratory environment. Due to this, and the lack of support voiced during the public comment process regarding efficacy or necessity, the NOSB recommended removal.

Comments received

AMS received no comments in support of keeping synthetic vitamin B₁ on the National List for organic crop production. One commenter requested the NOP allow for a 12-month implementation timeline.

AMS response

As commenters noted, the NOSB voted to remove vitamin B₁ from the National List at the Fall 2017 meeting on the basis that it is not essential for organic crop production and because its primary use for root growth and reduction of transplant shock was not substantiated by technical information. Given this information regarding use and efficacy, AMS is removing vitamin B₁ from the National List for organic crop production. Further, the 2015 technical report on vitamins for crop production identified several natural (nonsynthetic) alternatives to vitamin B₁, including yeast, various meals (e.g., soybean meal, cottonseed meal), and other crop waste or residues. After considering public comments, technical reports, and the NOSB review, AMS is finalizing

⁴ National Organic Standards Board, *Crops 2019 Sunset Substances*, <https://www.ams.usda.gov/sites/default/files/media/CS2019SunsetsFinalRec.pdf>

⁵ Pesticide Research Institute, *Technical Evaluation Report: Vitamins B₁, C and E*, <https://www.ams.usda.gov/sites/default/files/media/Vitamins%20B1-C-E%20TR%202015.pdf>

the removal of vitamin B₁ from the National List at § 205.601(j)(9). As specified in the DATES section, organic crop producers will have until March 15, 2023, to comply with this change.

Oxytocin (§ 205.603)

This final rule renews the allowance for oxytocin (an animal drug) for use in postparturition (birth) therapeutic applications at 7 CFR 205.603(a)(22). Oxytocin will not be prohibited, as proposed, in organic livestock production. A discussion of the compliant uses under the annotation, “postparturition therapeutic applications,” is included below in AMS’s response.

NOSB review and recommendation

Following its sunset review of oxytocin, the NOSB recommended removing oxytocin from the National List.⁶ As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

The NOSB requested public comment on whether the substance was essential for organic production and whether there were natural alternative materials and methods that render it unnecessary. In response, the NOSB received public comments indicating the substance was no longer necessary and generally supporting its removal. The NOSB concluded there are numerous alternative methods and materials to oxytocin and that the use of oxytocin no longer meets the criteria at 7 U.S.C. 6518(m)(6). Additionally, the NOSB noted that oxytocin is a synthetic hormone and that hormones are not otherwise permitted in organic production (§§ 205.237(b)(1) and 205.238(c)(3)).

⁶ National Organic Standards Board, *Livestock 2019 Sunset Substances*, <https://www.ams.usda.gov/sites/default/files/media/LS2019SunsetsFinalRec.pdf>

Comments received

AMS received several comments in response to the proposed sunset removal of oxytocin from the National List.

General opposition. A certifying agent (“certifier”) noted that 35 of the organic dairies they certify include the substance in their Organic System Plans for use in post-parturition therapeutic applications. The commenter stated that those operations use oxytocin for various uses, including uterine care, milk letdown for first-time heifers or as a mastitis treatment, retained placenta, and strained labor treatment. The commenter noted they do not allow routine or repeated use of oxytocin nor permit operations to use oxytocin to promote milk production. The commenter requested that any prohibition of the substance occur following the 2022 spring birthing season.

A dairy manufacturer requested retention for oxytocin on the National List due to a lack of alternatives. The commenter also stated oxytocin is a veterinary control drug that should only be administered or prescribed under veterinary instruction. The commenter recognized alternatives can assist with topical inflammation; however, for uses to assist with inflammation caused by animals withholding milk or to assist with uterine cleaning, the commenter stated there were no compliant alternatives. Another commenter also requested oxytocin to remain an allowed substance on account of its effectiveness as a post-parturition therapeutic to transition a dry cow to a lactating cow.

General agreement. A comment stated that natural alternatives are available to address certain post-parturition complications that can arise in organic dairy cattle and that use of oxytocin would prevent organic producers from claiming their products are “hormone-free.” The commenter requested an implementation period of 12 months to allow for industry time to comply with the final rule.

AMS response

After reviewing public comments, AMS is renewing the listing for oxytocin in this final rule. The substance will remain on the National List, with a new sunset date of March 15, 2027. AMS agrees with commenters that synthetic oxytocin remains essential to organic livestock production in the absence of alternative nonsynthetic (natural) medical treatments for post-parturition emergency treatments (i.e., treatment for severe complications resulting from labor). AMS notes that under current FDA regulations, “Federal law restricts [oxytocin] to use by or on the order of a licensed veterinarian.” (21 CFR 522.1680(c)(3)). Although some annotations on the National List for animal drugs specify that they may be used only by or on the order of a veterinarian, the absence of this phrasing in the annotation for oxytocin would not alter a producer’s obligations to comply with other federal laws.

By retaining oxytocin on the National List, organic livestock producers will continue to be permitted to use the drug to treat specific conditions within a limited timeframe following parturition without forfeiting the animal’s organic status. Additional discussion of the permitted uses of the substance in organic production follows.

Annotation discussion

AMS is aware there is some confusion around what uses comply with the annotation for oxytocin that reads, “use in postparturition therapeutic treatments” (§ 205.603(a)(22)). This discussion is meant to inform certifying agents and organic operations of AMS’s current thinking on uses that comply with the annotation.

The current annotation allows producers to use oxytocin to treat conditions related to labor and to an animal’s postpartum survival. Its use is not permitted on a routine basis (i.e., as protocol). Instead, it is available for emergency situations and severe complications in the immediate postpartum (following birth of young) period. It may not

be administered to increase an animal's milk production (volume) or for milk letdown. As previously noted in this document, Federal law restricts this drug to use by or on the order of a licensed veterinarian (21 CFR 522.1680(c)(3)).

AMS's interpretation of the annotation for oxytocin at § 205.603, "for postparturition therapeutic applications," is informed and supported by its prior discussion of oxytocin in its March 13, 2000 proposed rule (65 FR 13511). AMS believes that discussion is relevant to the meaning of the current annotation in the USDA organic regulations. In the discussion in the proposed rule, AMS noted that oxytocin, "has some uses that do not involve lactation but are instead related to an animal's postpartum survival" and that oxytocin was permitted by some certifiers for "animals that experience severe complications resulting from labor," and described those as "emergency situations" (65 FR 13511, 13588).

AMS's expectation is that certifiers will always review an organic operation's use of oxytocin to ensure it is used only in postparturition therapeutic applications.

Procaine (§ 205.603)

This final rule amends the National List to remove procaine at 7 CFR 205.603(b)(9) and prohibit its use in organic livestock production.

NOSB review and recommendation

Following the sunset review of procaine, the NOSB recommended removing procaine from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In support of their sunset review, the NOSB solicited public comment over two meetings on use of procaine and whether procaine can be sourced without prohibited antibiotics. The comments stated procaine is rarely used, is only available in drug

formulations that are combined with prohibited antibiotics, and is not as effective as lidocaine (allowed for organic livestock use at § 205.603(b)(5)). After their review, the NOSB recommended removal of procaine from the National List.

Comments received

AMS received no comments opposed to removing procaine from the National List. A certifying agent noted the importance of pain relievers but stated that procaine was not an active ingredient in any product currently used by organic operations that it certifies. Another comment highlighted that procaine products are already prohibited for use because they are always formulated with antibiotics that are prohibited in organic livestock production. One commenter requested an implementation timeline of 12 months to allow industry time to comply with the final rule.

AMS response

As the NOSB referenced in their recommendation, procaine is not available on its own (i.e., not compounded with an antibiotic). A search of the FDA's animal drug database (<https://animaldrugsatfda.fda.gov/>) indicates that all 16 of the FDA approved drugs that contain procaine also contain an antibiotic (e.g., Penicillin G Procaine). Furthermore, another National List material, lidocaine, could be used to perform the same function (as a local anesthetic). This information supports that procaine is not currently used in organic production and no longer meets the exemption requirement (7 U.S.C. 6517(c)(1)(A)(ii)). AMS agrees with commenters and the NOSB that procaine is not essential to organic livestock production. AMS is finalizing the removal of synthetic procaine from the National List at § 205.603(b)(9) to prohibit its use in organic livestock production. As specified in the DATES section, organic livestock producers will have until March 15, 2023, to comply with this change.

Alginic Acid (§ 205.605)

This final rule amends the National List to remove alginic acid at 7 CFR 205.605(b) and prohibit its use in organic processed products.

NOSB review and recommendation

Following the sunset review of alginic acid, the NOSB recommended removing alginic acid from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In support of their sunset review of alginic acid, the NOSB received a third-party technical report in 2015 and solicited public comment at their Spring 2019 meeting.⁷ The NOSB received no comments in support of continuing the allowance of, or stating use of, alginic acid. In addition, no certifying agents (“certifiers”) reported this material in use by their certified operations. Further, the 2015 technical report cited other National List materials (including agar-agar, carrageenan, gellan gum, and xanthan gum) as possible alternatives to alginic acid. Based on this, the NOSB determined that there are readily available alternatives and recommended removal.

Comments received

AMS received no comments in favor of retaining alginic acid on the National List. One comment agreed with the NOSB’s rationale for removing alginic acid from the National List and requested a 24-month implementation period to comply with the final rule.

AMS response

Given that there were no reports of operations using alginic acid and the availability of possible alternatives on the National List (as referenced in the technical

⁷ OMRI, *Technical Evaluation Report: Alginic Acid*, <https://www.ams.usda.gov/sites/default/files/media/Alginic%20Acid%20TR.pdf>

report), this substance no longer appears to meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). AMS is finalizing the removal of alginic acid from the National List at § 205.605(b) to prohibit its use in organic processed products. As identified in the DATES section, organic processors will have until March 15, 2024, to comply with this change.

Colors (§ 205.606)

This final rule amends the National List to remove eight nonorganic colors from the National List at § 205.606(d):

- Black currant juice color - derived from *Ribes nigrum* L.;
- Blueberry juice color - derived from blueberries (*Vaccinium spp.*);
- Carrot juice color - derived from *Daucus carota* L.;
- Cherry juice color - derived from *Prunus avium* (L.) L. or *Prunus cerasus* L.;
- Grape juice color - derived from *Vitis vinifera* L.;
- Paprika color - derived from dried powder or vegetable oil extract of *Capsicum annuum* L.;
- Pumpkin juice color - derived from *Cucurbita pepo* L. or *Cucurbita maxima* Duchesne;
- Turmeric extract color - derived from *Curcuma longa* L.

NOSB review and recommendation

The NOSB recommended the removal of these colors at their Fall 2020 meeting.⁸ The effect of these removals means that only organic forms of these colors will be allowed in organic handling. The NOSB solicited public comments in support of their sunset review of these colors at the Spring and Fall 2020 meetings. The NOSB noted these public comments were mixed regarding the availability and necessity of these

⁸ National Organic Standards Board, *2022 Sunset Reviews – Handling (§§ 205.605, 205.606)*, https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

colors. Additionally, in the case of carrot juice color and grape juice color, the NOSB noted that the availability of these crops in organic forms should provide an adequate supply of organic carrot juice and organic grape juice for color production and cited that as a reason for their recommended removal.

Comments received

AMS received few comments in response to the proposed removal of eight nonorganic colors from the National List.

General opposition. A comment requested retaining turmeric extract color on the National List because there is no readily available organic alternative in the marketplace. Another comment requested retaining paprika color on the National List as there are no commercially-available, organic alternatives for the color; however, the commenter stated there are readily-available, organic raw materials that may allow an organic version of the color to be developed. The commenter estimated a two-year implementation period would provide enough time for color development, shelf-life trials, and commercialization.

General agreement. A certifier noted limited use of the nonorganic colors in this final rule among the organic handlers they certify. The comment noted there is limited use of nonorganic paprika color, grape juice color, and cherry juice powder. A certifying agent was particularly concerned about an insufficient supply of blueberry juice color, carrot juice color, paprika color, and turmeric extract color. The commenter cited an internal survey (of organic operations) that indicated the supply of organic colors is fragile and that removal from the National List may be premature, especially without a substantial implementation period. The commenter requested an implementation timeline of 24 months to allow industry time to comply with the final rule.

AMS response

In the rule proposing removal of these colors, AMS requested comments regarding whether any of these colors are necessary and whether there are enough organic versions available to meet demand. Comments received suggested there may not be sufficient supplies of certain organic colors but that supply would likely develop over the course of the 24-month implementation period. None of these comments suggested an inability to produce or develop organic versions of these colors, given sufficient time. As such, AMS is finalizing the removal of these non-organic colors from the National List at § 205.606(d). To support the development of an adequate supply of organic colors, as requested by commentors, organic processors will have until March 15, 2024 (a 24-month implementation period) to comply with these changes.

Kelp (§ 205.606)

This final rule amends the National List to remove kelp at 7 CFR 205.606(k) and prohibit its use. Wakame seaweed and Pacific kombu remain allowed in § 205.606 in organic processed products.

NOSB review and recommendation

Following the sunset review of kelp at their Fall 2020 meeting, the NOSB recommended removing kelp from the National List. Only organic forms of kelp (other than wakame seaweed and Pacific kombu, which remain allowed in § 205.606), would be allowed in organic handling. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During its sunset review, the NOSB received comments in support of removing, as well as relisting, kelp. The NOSB determined that there were alternatives to kelp on

the National List (namely Pacific kombu and wakame) and therefore recommended removing kelp from the National List in § 205.606.

Comments received

AMS received no comments in favor of retaining nonorganic kelp on the National List for organic handling. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS response

According to the Organic Integrity Database, there are currently 104 certified crop, wild crop, and handling operations that list “kelp” as a certified organic product.⁹ Organic kelp appears to be commercially available; therefore, this substance is no longer necessary and no longer meets the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). AMS did not receive any comments challenging this conclusion and is finalizing the removal of non-organic kelp from the National List at § 205.606(k). As identified in the DATES section, organic processors will have until March 15, 2024, to comply with this change.

Konjac Flour (§ 205.606)

This final rule amends the National List to remove konjac flour at 7 CFR 205.606(l) and prohibit its use in organic processed products.

NOSB review and recommendation

Following the sunset review of konjac flour at their Fall 2017 meeting, the NOSB recommended removing konjac flour from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

⁹ Organic Integrity Database, accessed January 5, 2022: <https://organic.ams.usda.gov/integrity/Search.aspx>.

In support of their recommendation, the NOSB solicited public comment regarding the use and necessity of konjac flour in organic handling as well as the availability of organic konjac flour. The NOSB received little feedback from industry in response. One trade organization reported one organic producer using konjac flour but was unsure if it was for products sold as “organic.” Several certifiers stated they had not received any feedback from their clients regarding the need for, or use of, nonorganic konjac flour in their products. Ultimately, the NOSB voted to recommend removal of konjac flour from the National List at § 205.606(l) due to available alternatives.

Comments received

AMS received no comments in favor of retaining nonorganic konjac flour on the National List for organic handling. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS response

A search in the Organic Integrity Database for “konjac” shows 30 operations with some form of certified organic konjac products (e.g., powder, starch, konjac tubers).¹⁰ Given the lack of reported use of, or need for, nonorganic konjac flour, and the availability of organic konjac flour and konjac tubers, nonorganic konjac flour no longer meets the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). AMS did not receive any comments challenging this conclusion and, as such, is finalizing the removal of non-organic konjac flour from the National List at § 205.606(l). As identified in the DATES section, organic processors will have until March 15, 2024, to comply with this change.

Sweet Potato Starch (§ 205.606)

¹⁰ Organic Integrity Database, accessed January 5, 2022: <https://organic.ams.usda.gov/integrity/Search.aspx>.

This final rule amends the National List to remove sweet potato starch at 7 CFR 205.606(s)(2) and prohibit the use of non-organic sweet potato starch in organic products.

NOSB review and recommendation

Following the sunset review of sweet potato starch at their Fall 2020 meeting, the NOSB recommended removing sweet potato starch from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During its sunset review, the NOSB solicited public comment on the use and necessity of sweet potato starch but received little feedback. The comments suggested there is scant use of nonorganic sweet potato starch, that alternatives are readily available, and that organic sweet potato starch is available. Further, comments noted that the continued listing of nonorganic sweet potato starch is inhibiting production of organic forms of sweet potato starch. Based on this information, the NOSB recommended the removal of this substance due to available alternatives.

Comments received

AMS received no comments in favor of retaining nonorganic sweet potato starch on the National List for organic handling. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS response

A search in the Organic Integrity Database for “potato starch” shows 60 operations with some form of certified organic potato starch and another 27 operations with some form of certified organic pea starch, a cited alternative to sweet potato starch.¹¹ Given the low reported use of nonorganic sweet potato starch and the availability of

¹¹ Organic Integrity Database, accessed January 5, 2022: <https://organic.ams.usda.gov/integrity/Search.aspx>.

organic sweet potato starch and organic pea starch, nonorganic sweet potato starch no longer meets the requirements for inclusion on the National List at 7 U.S.C.

6517(c)(1)(A)(ii). AMS did not receive any comments challenging this conclusion and, as such, is finalizing the removal of non-organic sweet potato starch from the National List at § 205.606(s)(2). As identified in the DATES section, organic processors will have until March 15, 2024, to comply with this change.

Turkish Bay Leaves (§ 205.606)

This final rule amends the National List to remove Turkish bay leaves at 7 CFR 205.606(v) to prohibit its use in organic products.

NOSB review and recommendation

Following the sunset review of Turkish bay leaves at their Fall 2020 meeting, the NOSB recommended removing Turkish bay leaves from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During its sunset review, the NOSB received many comments supporting the removal of Turkish bay leaves due to the availability of organic versions. The NOSB called attention to one comment received at its Fall 2020 meeting from an organic producer who uses Turkish bay leaves in a wide range of organic canned soups. This food manufacturer noted that organic forms of Turkish bay leaves are readily available. Further comments from certifiers indicated that few, if any, of their operations use nonorganic Turkish bay leaves. Based on this information, the NOSB recommended the removal of this substance due to available alternatives.¹²

¹² National Organic Standards Board, *2022 Sunset Reviews – Handling (§§ 205.605, 205.606)*, https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

Comments received

AMS received no comments in favor of retaining nonorganic Turkish bay leaves on the National List for organic handling. A commenter noted that the NOSB received multiple comments supporting the removal of Turkish bay leaves from the National List during the 2020 sunset review. The commenter stated that Turkish bay leaves only remained on the National List after the NOSB's Fall 2015 meeting due to the lack of available, organic alternatives.

AMS response

Previously, AMS proposed removing Turkish bay leaves from § 205.606 following a Fall 2015 NOSB recommendation.¹³ At the time, AMS received comments stating organic whole Turkish bay leaves were not available in the quantity or quality to meet organic handling needs. As a result, AMS did not finalize removing Turkish bay leaves (82 FR 31241, July 6, 2017), and its sunset date was extended five years.

A search in the Organic Integrity Database for “bay leaves” shows 143 crop and handling operations with some form of certified organic bay leaves. A search using the term “Turkish bay leaves” shows six operations, as it appears that only one certifying agent identifies bay leaves with that level of specificity in the Organic Integrity Database.¹⁴ Given that comments to the NOSB indicated organic Turkish bay leaves are readily available in all forms and the high number of operations reported in the Organic Integrity Database with organic bay leaves (of which a subset are Turkish bay leaves), nonorganic Turkish bay leaves no longer meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). During this current rulemaking, AMS received no comments challenging this conclusion and is removing non-organic Turkish

¹³ National Organic Standards Board, *Sunset 2017 NOSB Final Review Handling Substances*, https://www.ams.usda.gov/sites/default/files/media/HS%202017%20Sunset%20Final%20Rvw%20605%28a%29_%28b%29_606_final%20rec.pdf

¹⁴ Organic Integrity Database, accessed January 5, 2022: <https://organic.ams.usda.gov/integrity/Search.aspx>.

bay leaves from the National List at § 205.606(v). As identified in the DATES section, organic processors will have until March 15, 2024, to comply with this change.

Whey Protein Concentrate (§ 205.606)

This final rule amends the National List to remove whey protein concentrate at 7 CFR 205.606(x) and prohibit its use in organic processed products.

NOSB review and recommendation

Following the sunset review of whey protein concentrate at their Fall 2020 meeting, the NOSB recommended removing whey protein concentrate from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During this sunset review, the NOSB received many comments supporting the removal of whey protein concentrate due to the availability of organic versions. The NOSB highlighted several commenters, who demonstrated that they produce a robust supply of organic whey protein concentrate in several forms and sell excess to the conventional market. A comment noted that the international supply chain of organic whey-based products is also robust. Further comments from at least one certifier indicated that none of their operations are using nonorganic whey protein concentrate. Based on this information, the NOSB recommended the removal of this substance based on available alternatives.¹⁵

Comments received

AMS received no comments in favor of retaining nonorganic whey protein concentrate on the National List for organic handling. A certifier noted that an organic

¹⁵ National Organic Standards Board, *2022 Sunset Reviews – Handling (§§ 205.605, 205.606)*, https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

operation they certify previously used non-organic whey protein concentrate but no longer does. Another commenter noted that the NOSB received many comments supporting the removal of whey protein from the National List during the 2020 sunset review, including from several manufacturers who demonstrated they produce a robust supply of organic whey protein concentrate. The commenter noted that removing the allowance of a nonorganic form will help support organic cheese manufacturers. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS response

Previously, AMS proposed removing whey protein concentrate from § 205.606, following a Fall 2015 NOSB recommendation.¹⁶ At that time, AMS received comments stating organic whey protein concentrate was essential for organic processed products and that there were no commercially available, organic products. As a result, AMS did not finalize the removal of whey protein concentrate from the National List (82 FR 31241, July 6, 2017).

A search in the Organic Integrity Database for “whey protein concentrate” shows 23 operations with some form of certified organic whey protein concentrate. The NOSB also received comments suggesting a substantial supply of all forms of organic whey protein concentrate and cited the diversion of some quantity to the conventional market as evidence that there is enough supply to meet the demand for organic whey protein concentrate. Given the comments submitted to the NOSB outlining the lack of use and stated abundance of supply, nonorganic whey protein concentrate no longer meets the requirement for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). During this current rulemaking, AMS received no comments challenging this conclusion and is

¹⁶ National Organic Standards Board, *Sunset 2017 NOSB Final Review Handling Substances*, https://www.ams.usda.gov/sites/default/files/media/HS%202017%20Sunset%20Final%20Rvw%20605%28a%29_%28b%29_606_final%20rec.pdf

removing non-organic whey protein concentrate from the National List at § 205.606(x). As identified in the DATES section, organic processors will have until March 15, 2024, to comply with this change.

III. Related Documents

AMS published notices in the Federal Register to announce the NOSB meetings where the Board discussed these substances. The notices invited public comments on the NOSB recommendations addressed in this final rule. Transcripts of the meetings, along with the NOSB recommendations, can be found on the AMS website at:

<https://www.ams.usda.gov/rules-regulations/organic/nosb/meetings>. The AMS proposed rule that preceded this final rule was published on August 24, 2021 (86 FR 47242).

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. The OFPA authorizes the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List (7 U.S.C. 6518 (k) and (n)). Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA (7 CFR 205.607). The current petition procedures published in the Federal Register (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Handbook on the NOP website as document NOP 3011 at <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

A. Executive Order 12866 and Regulatory Flexibility Act

This final rule does not meet the criteria of a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those Orders.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses.¹⁷ The SBA classifies small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$1,000,000 (13 CFR 121.201). Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector “all other professional, scientific, and technical services.” For this category, the small business threshold is average annual receipts of less than \$16.5 million.

Producers. AMS has considered the economic impact of this final rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics

¹⁷ “Table of Small Business Size Standards Matched to North American Industry Classification System Codes,” U.S. Small Business Administration, August 19, 2019, https://www.naics.com/wp-content/uploads/2017/10/SBA_Size_Standards_Table.pdf.

Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2017 Census of Agriculture, 16,585 organic farms in the United States reported sales of organic products and total farmgate sales more than \$9.9 billion.¹⁸ Based on that data, organic sales average just under \$600,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$1,000,000 sales threshold to qualify as a small business.

Handlers. According to the NOP’s Organic Integrity Database (OID), there are 10,971 U.S.-based organic handlers that are certified under the USDA organic regulations.¹⁹ The Organic Trade Association’s 2020 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: fewer than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA’s small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

Certifying agents. The SBA defines “all other professional, scientific, and technical services,” which include certifying agents, as those having annual receipts of less than \$16,500,000 (13 CFR 121.201). There are currently 76 USDA-accredited certifying agents, based on a query of the OID database, who provide organic certification services to producers and handlers. While many certifying agents are small entities that would be affected by this final rule, we do not expect that these certifying agents would incur significant costs as a result of this action as certifying agents already

¹⁸ “2019 Organic Survey,” 2017 Census of Agriculture, U.S. Department of Agriculture National Agricultural Statistics Service, table 1, https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Organics/ORGANICS.pdf.

¹⁹ Organic Integrity Database, U.S. Department of Agriculture, accessed October 27, 2021, <https://organic.ams.usda.gov/Integrity>.

must comply with the current regulations (e.g., maintaining certification records for organic operations).

AMS does not expect this rule to have a significant economic impact on entities affected by this rule. Alternatives exist to the substances that this rule prohibits, as determined by the NOSB and AMS. Additionally, AMS is providing a 12- to 24-month implementation period, depending on the substance or ingredient, to allow affected entities time to modify practices.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to the USDA to be accredited as a certifying agent, as described in the OFPA (7 U.S.C. 6514(b)). States are also preempted from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA (7 U.S.C. 6503–6507).

Pursuant to the OFPA (7 U.S.C. 6507(b)(2)), a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must: (a) Further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward

agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to 7 U.S.C. 6519(c)(6), this final rule does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056) concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

C. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, Office of Management and Budget (OMB) clearance is not required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This final rule has been reviewed under Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) Policies that have tribal implication, including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.

AMS has assessed the impact of this final rule on Indian tribes and determined that this rule would not have tribal implications that require consultation under Executive

Order 13175. AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed.

Information about the proposed changes to the regulations are shared during quarterly calls with Tribal leaders, who have the opportunity to submit comments. AMS works with the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the NOP regulations.

E. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

F. General Notice of Public Rulemaking

This final rule reflects recommendations submitted by the NOSB to the Secretary to remove fourteen nonorganic ingredients and two substances from the National List. This final rule retains (or “renews”) two substances on the National List.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6524.

2. Amend § 205.601 by revising paragraph (j)(9) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(j) * * *

(9) Vitamins, C and E.

* * * * *

§205.603 [Amended]

3. Amend § 205.603 by removing paragraph (b)(9) and redesignating paragraphs (b)(10) through 12 as paragraphs (b)(9) through (11):

§205.605 [Amended]

4. Amend § 205.605(b) by removing the words “Alginic acid (CAS #9005-32-7)”.

5. Amend § 205.606 by revising paragraphs (d) through (t) and removing paragraphs (u) through (w).

The revisions read as follows:

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

* * *

(d) Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(1) Beet juice extract color—derived from *Beta vulgaris* L., except must not be produced from sugarbeets.

(2) Beta-carotene extract color—derived from carrots (*Daucus carota* L.) or algae (*Dunaliella salina*).

(3) Black/purple carrot juice color—derived from *Daucus carota* L.

(4) Chokeberry, aronia juice color—derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.

(5) Elderberry juice color—derived from *Sambucus nigra* L.

(6) Grape skin extract color—derived from *Vitis vinifera* L.

- (7) Purple sweet potato juice color—derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.
- (8) Red cabbage extract color—derived from *Brassica oleracea* L.
- (9) Red radish extract color—derived from *Raphanus sativus* L.
- (10) Saffron extract color—derived from *Crocus sativus* L.
- (e) Cornstarch (native).
- (f) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606.
- (g) Fructooligosaccharides (CAS # 308066-66-2).
- (h) Gelatin (CAS # 9000-70-8).
- (i) Glycerin (CAS # 56-81-5) - produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).
- (j) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean).
- (k) Inulin-oligofructose enriched (CAS # 9005-80-5).
- (l) Lecithin - de-oiled.
- (m) Orange pulp, dried.
- (n) Orange shellac-unbleached (CAS # 9000-59-3).
- (o) Pectin (non-amidated forms only).
- (p) Potassium acid tartrate.
- (q) Seaweed, Pacific kombu.
- (r) Tamarind seed gum.
- (s) Tragacanth gum (CAS #-9000-65-1).
- (t) Wakame seaweed (*Undaria pinnatifida*).

* * * * *

Erin Morris,

Associate Administrator

Agricultural Marketing Service.

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